

**UNITED STATES DISTRICT COURT**  
**EASTERN DISTRICT OF NEW YORK**

WALLACE KEVIN EMERSON and  
CHRISTIE EMERSON,

Plaintiffs,

V.

MERCK & CO., INC. and  
MERCK SHARP &  
DOHME CORP.

Defendants.

Case No.:

## COMPLAINT AND DEMAND FOR JURY TRIAL

## COMPLAINT

**COMES NOW** Plaintiffs, Wallace Kevin Emerson and Christie Emerson, (“Plaintiff”),  
by and through their undersigned Counsel, and for their Complaint against the Defendants Merck  
& Co., Inc. and Merck Sharp & Dohme Corp. (collectively “Defendants”), allege as follows:

## NATURE OF THE CASE

1. This is an action for damages suffered by Plaintiff as a direct and proximate result of Defendant's wrongful conduct in connection with the development, design, testing, labeling, packaging, promoting, advertising, marketing, distribution, and selling of Defendants' prescription medication Propecia and Proscar.

2. Defendants manufacture and sell Propecia as a prescription treatment for androgenic alopecia.

3. Defendants manufacture and sell Proscar as a prescription treatment for benign prostate hyperplasia (“BPH”).

4. Defendants knew or should have known that Propecia and Proscar, when taken as prescribed and intended, causes and contributes to an increased risk of persistent and/or permanent serious and dangerous side effects including, without limitation, cognitive impairment, development of depression, and various forms of sexual dysfunction such as erectile dysfunction, reduced ejaculate volume, diminished or reduced libido, reduced sexual sensation, gynecomastia and/or infertility (“sexual dysfunction”) even after discontinuation of use.

### **JURISDICTION**

5. This Court has jurisdiction pursuant to 28 U.S.C. § 1332(a) because Plaintiff and Defendants are citizens of different States and the amount in controversy exceeds \$75,000 exclusive of interest and costs.

6. Venue in this action properly lies in this judicial district as the Judicial Panel on Multi District Litigation has established MDL 2331 and transferred actions to this District.

7. Venue in this action properly lies in this judicial district pursuant to 28 U.S.C. § 1391(a), as a substantial number of the events, actions or omissions giving rise to Plaintiff’s claims occurred in this district. At all times material hereto, Defendants conducted substantial business in this district.

### **PARTIES**

8. Plaintiff, Wallace Kevin Emerson, is a citizen of the state of Missouri, and a resident of Ozark City in the county of Christian County.

9. Plaintiff, Christie Emerson, is Plaintiff’s wife and is a citizen of the state of Missouri, and a resident of Ozark City in the county of Christian County.

10. Upon information and belief, Defendant Merck & Co., Inc. is a corporation organized and existing under the laws of New Jersey, and has its principal place of business located in Whitehouse Station, New Jersey.

11. Upon information and belief, Defendant Merck Sharp & Dohme Corp. is a corporation organized and existing under the laws of New Jersey, and has its principal place of business located in Whitehouse Station, New Jersey.

12. At all times relevant herein, Defendants tested, studied, researched, designed, formulated, manufactured, inspected, labeled, packaged, promoted, advertised, marketed, distributed, and sold the prescription drugs Propecia and Proscar in interstate commerce and throughout the Eastern District of New York. At all times relevant herein, Defendants were registered to do business in the Eastern District of New York.

### **GENERAL FACTUAL ALLEGATIONS**

13. Finasteride is the active ingredient in both Propecia and Proscar.

14. Propecia is prescribed in a 1 mg quantity.

15. Proscar is prescribed in a 5 mg quantity. Proscar may also be prescribed with the direction to the patient to split the pill into quarters, thereby administering a 1.25 mg quantity.

16. Finasteride was initially developed to treat patients with symptoms of benign prostatic hyperplasia ("BPH"), and then later approved for the treatment of androgenic alopecia, also known as male pattern hair loss.

17. Male pattern hair loss affects 30% of men by the age of 30 years and 50% of men by the age of 50 years. Men who suffer from hair loss may be perceived as older and less physically and socially attractive.

18. Male pattern hair loss is a common condition thought to be caused by a combination of genetic factors and a hormone called dihydrotestosterone ("DHT").

19. DHT is a substance in the body that can shrink hair follicles until a person no longer has hair on top of his head.

20. Finasteride is a Type 2 5- $\alpha$  reductase inhibitor that prevents the conversion of testosterone into dihydrotestosterone (“DHT”). Type 2 5- $\alpha$  reductase is predominant in the prostate, seminal vesicles, epididymis, and hair follicles as well as the liver, and is responsible for two-thirds of circulating DHT.

21. In the prostate, inhibition of 5 $\alpha$ -reductase leads to a reduction of prostate volume, which improves the symptoms of BPH. Finasteride (5 mg) has been found to reduce the Prostate-Specific Antigen (“PSA”) level by 50% from the baseline at the end of six months of therapy for BPH.

22. Finasteride may induce high-grade tumors by reducing levels of intracellular DHT within the prostate. Upon information and belief, prostate tumors that develop in men with low testosterone levels have higher-grade prostate cancer and worse outcomes than the prostate cancers that develop in men with normal testosterone levels.

23. Finasteride may produce undesirable side effects to patients who use the prescription drug, including but not limited to: sexual dysfunction that continues after discontinuation of treatment, including erectile dysfunction, libido disorders, ejaculation disorders, and orgasm disorders; breast cancer; prostate cancer; gynecomastia; and cognitive impairment.

24. The rates of the sexual dysfunction as a result of finasteride are reported to be as high as 39% in published clinical studies. In addition, it has been reported in 2003 that only 50% of patients experience resolution of their sexual function adverse events after discontinuation of finasteride.

**PROPECIA LABEL AND SIDE EFFECTS**

25. The U.S. Food and Drug Administration (“FDA”) initially approved finasteride in 1992 under the brand name Proscar as a treatment for BPH. Proscar is the brand name of the five (5) milligram tablet of finasteride.

26. In 1997, the FDA approved Propecia as a one (1) milligram tablet of finasteride for prescription use as a cosmetic treatment for male pattern hair loss.

27. Over one million people in the United States have used Propecia and/or Proscar since introducing the prescription drug into the U.S. market.

28. Defendants promote the use of Propecia and Proscar for treatment of male pattern hair loss as a safe treatment with minimal risk. In its product labeling, Defendants represent that a limited number of users may experience side effects including sexual dysfunctions such as decreased libido, erectile dysfunction, and ejaculation disorder and gynecomastia as well as potential depression.

29. After approval, the Propecia label stated the following regarding sexual adverse effects:

[t]he following clinical adverse reactions were reported as possibly, probably or definitely drug-related in  $\geq 1\%$  of patients treated for 12 months with PROPECIA or placebo, respectively: decreased libido (1.8%, 1.3%), erectile dysfunction (1.3%, 0.7%) and ejaculation disorder (1.2%, 0.7%; primarily decreased volume of ejaculate: [0.8%, 0.4%]).

30. By 2003, the medical literature was reporting that the rates of erectile dysfunction in men taking Finasteride was between 1% and 33%, and randomized controlled clinical studies report rates of erectile dysfunction with use of 5-alpha-reductase inhibitors to be between 0.8% - 15.8%.

31. In September 2003, Defendants updated its Proscar label to include isolated reports of male breast cancer in the Adverse Reactions, Long-Term Treatment section.

Additionally, Defendants updated the Precautions subsection to instruct patients to promptly report any changes in their breasts, such as lumps, pain or nipple discharge to their physician.

32. In 2006, the Swedish Medical Products Agency began investigating reports of persistent sexual dysfunctions that continued in men despite discontinuing Finasteride.

33. In 2008, Defendants changed the Propecia label in Sweden to include the following warning:

In addition, the following have been reported in post-marketing use: persistence of erectile dysfunction after discontinuation of treatment with PROPECIA.

34. In August 2009, the Swedish Medical Products Agency concluded that Propecia could lead to permanent erectile dysfunction.

35. Upon information and belief, Defendants have also changed the Propecia label in other European countries, including the United Kingdom and Italy, to include a warning of persistent and/or permanent erectile dysfunction after discontinuation of treatment

36. The Medicine Health Care Products Regulatory Agency public assessment report on the risk of finasteride published in December of 2009 stated that, “In addition, the following have been reported in post-marketing use: persistence of ED after discontinuation of treatment with PROPECIA.” (Section 4.8 Undesirable Effects).

37. In a 1996 letter to the New England Journal of Medicine, Doctors Lanh Green, R.Ph., M.P.H., Diane K. Wysowski, Ph.D., and Jean L. Fourcroy, M.D., Ph.D stated that gynecomastia can be attributed to use of finasteride. Specifically, they said:

Finasteride blocks the conversion of testosterone to dihydrotestosterone. Because gynecomastia is due to an increased ratio of estrogen to androgen, it is biologically plausible that finasteride causes gynecomastia.

38. A 2011 article by *Traish, et al.* reported on the results of a seven year study:

In the Prostate Cancer Prevention Trial (PCPT), approximately 426 of 9,423 subjects (4.5%) in the Finasteride arm had gynecomastia compared with 261 of 9,457 subjects (2.8%) in the placebo arm.

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Inhibition of  $5\alpha$ -DHT synthesis by  $5\alpha$ -RIs may shift metabolism of T toward estradiol ( $E_2$ ) and alter the estrogen to androgen ratio, thus increasing the risk of gynecomastia and male breast cancer.

39. In 2009, the United Kingdom regulatory agency provided a warning about the risk of prostate cancer when using 5 milligram Finasteride, such as Proscar.

40. In October 2010, Defendants updated its Proscar label to include male breast cancer in the Adverse Reactions Postmarketing Experience section of the Package Insert and corresponding possible side effects section of the Patient Package Insert.

41. In March of 2011, Defendants updated its Propecia label to include the term depression to the Adverse Reactions Postmarketing Experience section of the labeling and Patient Package Insert.

42. In April of 2011, Defendants updated its “Patient Information About Propecia” insert to indicate patients have reported “difficulty in achieving an erection that continued after stopping the medication.” Upon information and belief, Defendants updated insert is the first warning it gave to patients in the U.S. regarding persistent and/or permanent sexual dysfunction after discontinuation of use. Additionally, Defendants updated its Propecia label to include male breast cancer in the Adverse Reactions, Postmarketing Experience section of the labeling and Patient Package Insert.

43. In June 2011, Defendants updated their Proscar label to include a warning about the risk of high-grade prostate cancer and high serum prostate specific antigen (“PSA”) levels for the first time.

44. This announcement followed the FDA's Oncologic Drugs Advisory Committee's vote of 17-0 in December 2010 that Merck's Finasteride should not be used to prevent prostate cancer because the drug is linked to a higher incidence of high-grade tumors.

45. In March, 2012, Health Canada informed health professionals that Finasteride may be associated with an increased risk of developing certain forms of prostate cancer.

46. In March, 2012, new warnings were added to Propecia and Proscar labels in Canada to reflect the increased risk of prostate cancer found in Health Canada's review of two large international clinical trials: the Prostate Cancer Prevention Trial (PCPT) and the Reduction by Dutasteride of Prostate Cancer Events (REDUCE) trial.

47. In April 2012, Defendants updated their Propecia and Proscar labels to include a warning about the risk of erectile dysfunction that continued after discontinuation of treatment in their Adverse Reactions, Postmarketing Experience sections of the labeling and Patient Package Insert.

#### **SPECIFIC FACTUAL ALLEGATIONS**

48. In 2006, Plaintiff Kevin Wallace Emerson was 35 years of age when he was prescribed and began consuming Propecia for male pattern hair loss. Plaintiff started taking Propecia on or about June of 2006 and stopped taking it on or about August of 2007.

49. Neither Plaintiff, nor his physician, received an adequate warning from Defendants about the risk of persistent and/or permanent injury after discontinuation of treatment.

50. While consuming Propecia, Plaintiff began to suffer and was diagnosed with erectile dysfunction and related sexual dysfunction.

51. To date, Plaintiff has stopped taking Propecia but continues to suffer from adverse side effects, including but not limited to, sexual dysfunction and cognitive impairment. As a



direct and proximate cause of his Propecia-induced side effects, Plaintiff has suffered significant pain and suffering, and his quality of life has been severely diminished.

52. As a result of Plaintiff's use of Propecia, Plaintiff requires ongoing treatment, including without limitation, regular medical monitoring.

**FIRST CAUSE OF ACTION**  
**STRICT LIABILITY**

53. Plaintiff incorporates by reference each and every paragraph of this Complaint as if fully set forth herein and further alleges as follows:

54. At all relevant times hereto, Defendants were engaged in the development, testing, manufacturing, marketing and sales of Propecia and Proscar. Defendants designed, manufactured, marketed, and sold Propecia and Proscar to medical professionals and their patients, knowing it would be ingested for the treatment of male pattern hair loss.

55. Propecia and/or Proscar as designed, manufactured, marketed and sold by Defendants reached Plaintiff without substantial change in its condition and was used by Plaintiff in a reasonably foreseeable and intended manner.

56. Propecia and/or Proscar was "defective" and "unreasonably dangerous" when it entered the stream of commerce and was received by Plaintiff, because it was dangerous to an extent beyond that which would be contemplated by the ordinary consumer. At no time did Plaintiff have reason to believe that Propecia and/or Proscar was in a condition not suitable for its proper and intended use among patients.

57. Propecia and/or Proscar was used in the manner for which it was intended, that is, for treatment of male pattern hair loss. This use resulted in injury to Plaintiff.

58. Plaintiff was not able to discover, nor could he have discovered through the exercise of reasonable care, the defective nature of Propecia and/or Proscar. Further, in no way

could Plaintiff have known that Defendants had designed, developed, and manufactured Propecia and/or Proscar in such a way as to increase the risk of harm or injury to the recipients of Propecia and/or Proscar.

59. Propecia and Proscar are defective in design because of their propensity to cause persistent and/or permanent sexual dysfunction side effects, gynecomastia and other indefinite injuries after discontinuation of use.

60. Propecia and/or Proscar is unreasonably dangerous because it was sold to Plaintiff without adequate warnings regarding, *inter alia*, the propensity of Propecia and/or Proscar to cause persistent sexual side effects after discontinuation of use; the post-marketing experience with Propecia and/or Proscar; and the numbers of persistent sexual adverse events reported.

61. Defendants failed to develop and make available alternative products that were designed in a safe or safer manner, even though such products were feasible and marketable at the time Defendants sold Propecia and/or Proscar to Plaintiff.

62. Defendants had knowledge and information confirming the defective and dangerous nature of Propecia and Proscar. Despite this knowledge and information, Defendants failed to adequately and sufficiently warn Plaintiff and his physicians that Propecia and/or Proscar causes serious persistent and/or permanent injuries including, without limitation, sexual dysfunction and gynecomastia and cognitive impairment after discontinuation of use.

63. As a direct and proximate result of Defendants' wrongful conduct, including Propecia and Proscar's defective and dangerous design and inadequate warnings, Plaintiff has sustained and will continue to sustain severe and debilitating injuries, pain and suffering, economic loss, and other damages including, but not limited to, cost of medical care, rehabilitation, and treatments for depression, emotional distress, and anxiety, for which he is

entitled to compensatory and equitable damages and declaratory relief in an amount to be proven at trial.

**SECOND CAUSE OF ACTION**  
**DEFECTIVE DESIGN**

64. Plaintiff incorporates by reference each and every paragraph of this Complaint as if fully set forth herein and further alleges as follows:

65. At all relevant times, Defendants had a duty to exercise reasonable care in the design, formulation, testing, manufacture, marketing, sale, and distribution of Propecia and Proscar, including a duty to ensure that Propecia and Proscar did not pose a significantly increased risk of persistent and/or permanent injury to its users.

66. The subject product was defective in its design and was unreasonably dangerous in that its foreseeable risks exceeded the benefits associated with its design or formulation.

67. At the time Defendants manufactured, designed, distributed, sold, and/or supplied the Propecia and/or Proscar into the stream of commerce, safer, more practical, alternative designs were available, including but not limited to prescription drug alternatives and non-prescription drug alternatives,

68. Although Defendant actually knew of the defective nature of the subject product, it continued to design, manufacture, market, and sell it so as to maximize sales and profits at the expense of the public health and safety, in knowing, conscious and deliberate disregard of the foreseeable harm caused by the subject product.

69. As a direct and proximate result of Defendants' failure to identify and subsequently address and fix the defective nature of its product, Plaintiff ingested Propecia and/or Proscar and suffered severe and debilitating injuries, pain and suffering, and economic loss, and other damages including, but not limited to, cost of medical care, rehabilitation, and

treatments for depression, emotional distress, and anxiety, for which he is entitled to compensatory and equitable damages and declaratory relief in an amount to be proven at trial.

**THIRD CAUSE OF ACTION**  
**FAILURE TO WARN**

70. Plaintiff incorporates by reference all preceding paragraphs as if fully set forth herein and further allege on information and belief as follows.

71. Before Plaintiff ingested Propecia during the period in which they used the drugs, Defendants knew or had reason to know that Propecia and Proscar were dangerous drugs that created an unreasonable risk of bodily harm to consumers.

72. Defendants had a duty to exercise reasonable care to warn end users of the dangerous conditions or of the facts that made Propecia and Proscar likely to be dangerous, including permanent sexual dysfunction and gynecomastia

73. Despite the fact that Defendants knew or had reason to know that Propecia and Proscar were dangerous, Defendants failed to exercise reasonable care in warning the medical community and consumers, including Plaintiff, of the dangerous conditions and facts that made Propecia and Proscar likely to be dangerous.

74. The Plaintiff' injuries were the direct and proximate result of Defendants' failure to warn of the dangers of Propecia and Proscar.

75. Defendants' conduct, as described above, was extreme and outrageous. Defendants endangered the health of consumers and users of their products, including Plaintiff, with knowledge of the safety and efficacy problems and suppressed this knowledge from the general public. Defendants made conscious decisions not to redesign, re-label, warn or inform the unsuspecting consuming public. Defendants' outrageous conduct warrants an award of punitive damages.

76. As a direct and proximate result of Defendants' acts and omissions, including their failure to exercise ordinary care in the design, formulation, testing, manufacture, sale, and distribution of Propecia and Proscar, Plaintiff ingested Propecia and/or Proscar and suffered severe and debilitating injuries, pain and suffering, and economic loss, and other damages including, but not limited to, cost of medical care, rehabilitation, and treatments for depression, emotional distress, and anxiety, for which he is entitled to compensatory and equitable damages and declaratory relief in an amount to be proven at trial.

**FOURTH CAUSE OF ACTION**  
**NEGLIGENCE**

77. Plaintiff incorporates by reference each and every paragraph of this Complaint as if fully set forth herein and further alleges as follows:

78. At all relevant times, Defendants had a duty to exercise reasonable care in the design, formulation, testing, manufacture, marketing, sale, and distribution of Propecia and Proscar, including a duty to ensure that Propecia and Proscar did not pose a significantly increased risk of persistent and/or permanent serious and dangerous side effects including, without limitation, cognitive impairment, development of depression, prostate cancer, breast cancer, gynecomastia and various forms of sexual dysfunction during and after discontinuation of use.

79. Defendants had a duty to exercise reasonable care in the advertising and sale of Propecia and/or Proscar, including a duty to warn Plaintiff and other consumers, of the dangers associated with the consumption of Propecia and Proscar that were known or should have been known to Defendants at the time of the sale of Propecia and/or Proscar to the Plaintiff.

80. Defendants failed to exercise reasonable care in the design, testing, manufacture, marketing, sale and distribution of Propecia and Proscar because Defendants knew or should

have known that Propecia and Proscar had a propensity to cause serious injury, including increased risk of persistent and/or permanent serious and dangerous side effects including, without limitation, cognitive impairment, development of depression, prostate cancer, breast cancer, gynecomastia and various forms of sexual dysfunction during and after discontinuation of use.

81. Defendants failed to exercise ordinary care in the labeling of Propecia and Proscar and failed to issue adequate pre-marketing or post-marketing warnings to prescribing doctors and the general public regarding the risk of serious injury, including, without limitation, cognitive impairment, development of depression, prostate cancer, breast cancer, gynecomastia and various forms of sexual dysfunction during and after discontinuation of use.

82. Defendants knew or should have known that Plaintiff could foreseeably suffer injury as a result of Defendants' failure to exercise ordinary care as described above.

83. Defendants breached their duty of reasonable care to Plaintiff by failing to exercise due care under the circumstances.

84. As a direct and proximate result of Defendants' acts and omissions, including their failure to exercise ordinary care in the design, formulation, testing, manufacture, sale, and distribution of Propecia and Proscar, Plaintiff ingested Propecia and/or Proscar and suffered severe and debilitating injuries, pain and suffering, and economic loss, and other damages including, but not limited to, cost of medical care, rehabilitation, and treatments for depression, emotional distress, and anxiety, for which he is entitled to compensatory and equitable damages and declaratory relief in an amount to be proven at trial.

**FIFTH CAUSE OF ACTION**  
**BREACH OF IMPLIED WARRANTIES**

85. Plaintiff incorporates by reference each and every paragraph of this Complaint as if fully set forth herein and further alleges as follows:

86. Defendants designed, formulated, tested, manufactured, marketed, sold, and distributed Propecia and Proscar as has previously been alleged and described herein.

87. At the time Defendants marketed, sold and distributed Propecia and Proscar, Defendants knew of the use for which Propecia and Proscar was intended and impliedly warranted that Propecia and Proscar was merchantable, safe and fit for its intended purpose: namely that Plaintiff could ingest Propecia and/or Proscar without the risk of serious persistent and/or permanent sexual dysfunction gynecomastia and cognitive impairment after discontinuation of use.

88. Plaintiff, foreseeable user of Propecia and/or Proscar, and Plaintiff's physician(s), reasonably relied upon Defendants' judgment and implied warranties in purchasing and consuming Propecia as intended.

89. Propecia and/or Proscar was defective, unmerchantable, and unfit for ordinary use when sold, and subjected Plaintiff to severe and permanent injuries.

90. Defendants breached their implied warranties because Propecia and Proscar were and continue to be neither of merchantable quality nor safe for its intended use in that Propecia and Proscar have the propensity to cause persistent sexual dysfunction, gynecomastia and other bodily harm after discontinuation of use.

91. As a direct and proximate result of Defendants' breach of the implied warranties of merchantability and fitness for its intended purpose, Plaintiff ingested Propecia and/or Proscar and suffered severe and debilitating injuries, pain and suffering, and economic loss, and other

damages including, but not limited to, cost of medical care, rehabilitation, and treatments for depression, emotional distress, and anxiety, for which he is entitled to compensatory and equitable damages and declaratory relief in an amount to be proven at trial.

**SIXTH CAUSE OF ACTION**  
**BREACH OF EXPRESS WARRANTY**

92. Plaintiff incorporates by reference each and every paragraph of this Complaint as if fully set forth herein and further alleges as follows:

93. Defendants through their marketing program, promotional activities, product labeling, package inserts, and other written and verbal assurances expressly warranted to physicians and consumers, including Plaintiff and/or his physicians, that Propecia and Proscar had been shown by scientific study to be safe for its intended use.

94. Plaintiff, and/or his physicians, reasonably relied upon Defendants' express warranties in purchasing consuming, and prescribing Propecia and/or Proscar.

95. Defendants breached their express warranties because Propecia and Proscar as manufactured and sold by Defendants does not conform to these express representations in that Propecia and/or Proscar have a propensity to cause persistent sexual function, gynecomastia and other bodily harm after discontinuation of use.

96. As a direct and proximate result of Defendants' breach of their express warranties, Plaintiff ingested Propecia and/or Proscar and suffered severe and debilitating injuries, pain and suffering, and economic loss, and other damages including, but not limited to, cost of medical care, rehabilitation, and treatments for depression, emotional distress, and anxiety, for which he is entitled to compensatory and equitable damages and declaratory relief in an amount to be proven at trial.



**SEVENTH CAUSE OF ACTION**  
**FRAUD**

97. Plaintiff incorporates by reference each and every paragraph of this Complaint as if fully set forth herein and further alleges as follows:

98. Defendants were under a duty and failed to discharge their duty to exercise reasonable care to disclose to Plaintiff and his doctors the defective nature and risks that Propecia and/or Proscar can cause severe and permanent injuries, including, without limitation, persistent and/or permanent sexual dysfunction, gynecomastia and cognitive impairment after discontinuation of use, of which they had special knowledge not available to Plaintiff or his doctors, and as to which they made affirmative representations in violation of all applicable laws, and concealed material facts relating to the defective nature and risks of Propecia and/or Proscar, which were peculiarly within its knowledge, knowing that Plaintiff and his doctors would rely on the presumption that no such facts exist.

99. Defendants knew that Propecia and Proscar can cause severe injuries, including, without limitation, persistent and/or permanent sexual dysfunction, gynecomastia and cognitive impairment; indeed, Defendants knew that persistent and/or permanent sexual side effects associated with Propecia and/or Proscar had occurred for years. Defendants had actual knowledge at the time of sale of Propecia and/or Proscar to the Plaintiff that Propecia and/or Proscar created a risk of serious bodily injury to its users, including, without limitation, persistent sexual dysfunction side effects, gynecomastia and cognitive impairment, based, in part, upon test results, studies, adverse reaction reports, regulatory action in foreign countries, published reports, and their own clinical trials and post-marketing surveillance of Propecia and Proscar.

100. At all times during the course of dealing between Defendants and Plaintiff, Defendants knowingly and recklessly omitted and concealed information peculiarly within their knowledge to the Plaintiff, his doctors, the scientific community and to the general public - e.g., the dangers of Propecia and/or Proscar, including the special risk of persistent and/or permanent sexual dysfunction and cognitive impairment after discontinuation of use - knowing that the scientific community, the general public, the Plaintiff and his doctors, would rely on the presumption that the dangers did not exist.

101. Defendants actively concealed from the Plaintiff, his doctors, the scientific community and the general public:

- i. that their own test results, published studies, and/or clinical trials showed a risk of serious injuries associated with Propecia and Proscar including, without limitation, persistent and/or permanent sexual dysfunction, gynecomastia and cognitive impairment after discontinuation of use; and/or
- ii. that Propecia and Proscar were not adequately tested for persistent and/or permanent sexual dysfunction, gynecomastia or cognitive impairment before or after its introduction on the market; and/or
- iii. that Propecia and Proscar were, in fact, unsafe as it posed a risk of persistent and/or permanent injury which outweighed any purported benefits.

102. Defendants misrepresented that Propecia and Proscar were safe and effective for their intended uses by affirmative misrepresentation, and/or actively concealment and omission of material facts regarding the safety and effectiveness of Propecia and Proscar, and by their course of conscious or intentional conduct succeeded in selling and marketing a drug with persistent and/or permanent adverse effects to be ingested by Plaintiff. Defendants intentionally

omitted, concealed and/or suppressed this information from consumers, including Plaintiff and his doctors, in order to avoid losses in sales to consumers and market share to its major competitors.

103. Moreover, Defendants engaged in an aggressive marketing strategy, which included false representations regarding the adverse side effects of Propecia and Proscar, to create the impression and to convey to Plaintiff and the general public that:

- i. Propecia and Proscar had a favorable safety profile and was fit for human consumption;
- ii. the benefits of taking Propecia and Proscar outweighed any associated risks; and
- iii. the use of Propecia and Proscar was safe and had fewer adverse health and side effects than were known or should have been known by Defendants at the time of these representations.

104. The omissions, misrepresentations and concealment described in the preceding paragraphs occurred, without limitation, in the Propecia and Proscar warning labels, advertisements and promotional materials, in the Defendants funded or created scientific reports, and the failure to provide other special notification of the dangers of Propecia and/or Proscar to the Plaintiff or his physicians, for example, Dear Doctor letters. The Defendants' statements omitted, concealed, and misrepresented the dangers of serious injury, including, but not limited to, persistent and/or permanent sexual dysfunction and cognitive impairment after discontinuation of use to Plaintiff and his prescribing doctors.

105. Defendants engaged in fraud by deliberately and affirmatively concealing and failing to disclose adverse reactions of Propecia and/or Proscar to Plaintiff, his doctors, the

scientific community, and the general public, and by disseminating only positive and misleading scientific data, and by concealing scientific data that showed increased risk of persistent and/or permanent injury after discontinuation of use, to Plaintiff, his doctors, the scientific community, and the general public.

106. Plaintiff, and his prescribing physician, relied on the warning labels as they appeared in the patient package insert at the time they prescribed or consumed Propecia and/or Proscar. The applicable warnings concealed and omitted material facts relating to the defective nature and risks of Propecia and/or Proscar. These dangers were peculiarly within the Defendants' knowledge, and were omitted and concealed knowing that Plaintiff and his doctors would rely on the presumption that no such facts exist.

107. Defendants knew or should have known that their representations and omissions regarding the safety of Propecia and/or Proscar were, in fact, false and/or misleading, and actively made such representations and omissions with the intent, design, and purpose that Plaintiff and others, including prescribing physicians, rely on these representations leading to the prescription, purchase and consumption of Propecia and/or Proscar.

108. At all times herein, Plaintiff and his physicians were unaware of the dangers of Propecia and/or Proscar with respect to persistent and/or permanent serious and dangerous side effects, including, without limitation, without limitation, cognitive impairment, development of depression, prostate cancer, breast cancer, gynecomastia and various forms of sexual dysfunction during and after discontinuation of use, and were reasonably misled by the Defendants' omission of information about these dangers.

109. At all times herein, Plaintiff and his physicians were unaware of the falsity underlying Defendants' statements and reasonably believed Defendants' false statements about the safety and efficacy of Propecia and/or Proscar to be true.

110. Plaintiff and his doctors could not have discovered Defendants' fraudulent and misleading conduct at an earlier date through the exercise of reasonable diligence because Defendants actively concealed their deceptive, misleading and unlawful activities.

111. Plaintiff and his physicians did, and could be expected to, reasonably and justifiably rely on Defendants' representations and omissions because Defendants held themselves out as having expertise and specialized knowledge in the pharmaceutical industry.

112. Plaintiff justifiably relied upon to his detriment and/or was induced by Defendants' false statements and active concealment over the safety of Propecia and/or Proscar, in part, because at no time did Plaintiff or his physicians have the knowledge or expertise necessary to independently evaluate the safety of Propecia and/or Proscar.

113. Defendants' misrepresentations, concealment, suppression and omissions were made willfully, wantonly, uniformly, deliberately, or recklessly, in order to induce Plaintiff to purchase Propecia and/or Proscar and Plaintiff and his physicians did reasonably and justifiably rely upon the material misrepresentations and missions made by the Defendants about Propecia and/or Proscar when agreeing to purchase and/or ingest Propecia and/or Proscar.

114. As a direct and proximate result of Defendants' false representations and/or active concealment of material facts regarding the safety and efficacy of Propecia, Plaintiff ingested Propecia and/or Proscar and suffered severe and debilitating injuries, pain and suffering, and economic loss, and other damages including, but not limited to, cost of medical care, rehabilitation, and treatments for depression, emotional distress, and anxiety, for which he is

entitled to compensatory and equitable damages and declaratory relief in an amount to be proven at trial.

**EIGHTH CAUSE OF ACTION**  
**FRAUDULENT CONCEALMENT**

115. Any applicable statutes of limitations have been tolled by the knowing and active concealment and denial of material facts known by each defendant when it had a duty to disclose those facts. Each defendant has kept plaintiff ignorant of vital information essential to its pursuit of these claims, without any fault or lack of diligence on plaintiff's part, for the purpose of obtaining delay on plaintiff's part in filing a complaint on their causes of action. Each defendant's fraudulent concealment did result in such delay. Plaintiff could not reasonably have discovered these claims until shortly before filing her original complaint.

116. Each defendant was under a continuing duty to disclose the true character, quality, and nature of its drug that Plaintiff ingested, but instead concealed them. As a result, each defendant is estopped from relying on any statute of limitations defense.

**NINTH CAUSE OF ACTION**  
**VIOLATION OF UNFAIR AND DECEPTIVE TRADE PRACTICES ACTS**

117. Plaintiff incorporates by reference each and every paragraph of this Complaint as if fully set forth herein and further alleges as follows:

118. Defendants have a statutory duty to refrain from unfair or deceptive acts or trade practices in the design, development, manufacture, promotion, and sale of Propecia and Proscar.

119. Had the Defendants not engaged in the deceptive conduct described herein, Plaintiff would not have purchased and/or paid for Propecia and/or Proscar, and would not have incurred related medical costs. Specifically, Plaintiff, his physician, and his staff were misled by the deceptive conduct described herein.

120. Defendants' deceptive, unconscionable, and/or fraudulent representations and material omissions to patients, physicians and consumers, including Plaintiff, constituted unfair and deceptive acts and trade practices in violation of the state consumer protection statute listed below.

121. Defendants engaged in wrongful conduct while at the same time obtaining, under false pretenses, substantial sums of money from Plaintiff for Propecia and/or Propecia that they would not have paid had Defendants not engaged in unfair and deceptive conduct.

122. Defendants have engaged in unfair competition or unfair or deceptive acts or practices or made false representation in violation of New York General Business Law § 349 et seq. and § 350 et seq.

123. Plaintiff was injured by the cumulative and indivisible nature of Defendants' conduct. The cumulative effect of Defendants' conduct directed at patients, physicians and consumers was to create a demand for and sell Propecia and Proscar. Each aspect of Defendants' conduct combined to artificially create sales of Propecia and Proscar.

124. The medical community relied upon Defendants' misrepresentations and omissions in determining to use Propecia and Proscar.

125. By reason of the unlawful acts engaged in by Defendants, Plaintiff has suffered ascertainable loss and damages.

126. As a direct and proximate result of Defendants' wrongful conduct, Plaintiff was damaged by paying in whole or in part for Propecia and/or Proscar.

127. As a direct and proximate result of Defendants' violations of the District of Columbia's unfair trade practice acts, Plaintiff has sustained economic losses and other damages

for which he is entitled to statutory and compensatory damages, and declaratory relief, in an amount to be proven at trial.

**TENTH CAUSE OF ACTION**  
**NEGLIGENT INFLICTION OF EMOTIONAL DISTRESS**

128. Plaintiff incorporates by reference each and every paragraph of this Complaint as if fully set forth herein and further alleges as follows:

129. Defendants carelessly and negligently manufactured, marketed, and sold Propecia and/or Proscar to Plaintiff, carelessly and negligently concealed these defects from Plaintiff, and carelessly and negligently misrepresented the quality and safety of Propecia and/or Proscar. Defendants should have realized that such conduct involved an unreasonable risk of causing emotional distress to reasonable persons, that might, in turn, result in illness or bodily harm.

130. Defendants owed a duty to treating physicians and Plaintiff to accurately and truthfully represent the risks of Propecia and/or Proscar. Defendants breached that duty by misrepresenting and/or failing to adequately warn of the risks of Propecia and/or Proscar – effects of which Defendants knew or in the exercise of diligence should have known – to the treating physicians and Plaintiff.

131. As a direct and proximate result of Defendants' wrongful conduct and breach of duty, Plaintiff has sustained and will continue to sustain severe emotional distress either due to physical injury or a rational fear of physical injury and is entitled to recovery of damages in an amount to be proven at trial. Defendants are liable to Plaintiff jointly and/or severally for all general, special and equitable relief to which Plaintiff is entitled by law in an amount to be proven at trial.



**ELEVENTH CAUSE OF ACTION**  
**INTENTIONAL INFLICTION OF EMOTIONAL DISTRESS**

132. Plaintiff incorporates by reference each and every paragraph of this Complaint as if fully set forth herein and further alleges as follows:

133. Defendants' conduct in continuing to market, sell, and distribute Propecia and Proscar after obtaining knowledge they cause significant risk of sexual dysfunction and serious persistent and/or permanent injuries including, without limitation, increased risk of persistent and/or permanent serious and dangerous side effects including, without limitation, cognitive impairment, development of depression, prostate cancer, breast cancer, and various forms of sexual dysfunction during and after discontinuation of use, showed extreme and outrageous, intentional, willful, and reckless conduct while evidencing a complete indifference to, or a conscious disregard for, the safety of others justifying an award of additional damages for aggravating circumstances in such a sum which will serve to deter Defendants and others from similar conduct in the future.

134. Plaintiff suffered severe emotional distress, which was a direct and proximate result of Defendants' extreme and outrageous, intentional, willful, and reckless conduct with the development, design, testing, labeling, packaging, promoting, advertising, marketing, distribution, and selling of Defendants' prescription medications Propecia and Proscar for the treatment of male pattern hair loss and BPH.

**WHEREFORE**, Plaintiff prays for relief against Defendants, jointly and severally, as follows:

1. Compensatory damages, in excess of the amount required for federal diversity jurisdiction, and in an amount to fully compensate Plaintiff for all his injuries and damages, both past and present;

2. Special damages, in excess of the amount required for federal diversity jurisdiction and in an amount to fully compensate Plaintiff for all of his injuries and damages, both past and present, including but not limited to, past and future medical expenses, costs for past and future rehabilitation and/or home health care, lost income, permanent disability, including permanent instability and loss of balance, and pain and suffering.

3. Punitive and/or exemplary damages for the wanton, willful, fraudulent, reckless acts of Defendant who demonstrated a complete disregard and reckless indifference for the safety and welfare of the general public and to Plaintiff in an amount sufficient to punish Defendant and deter future similar conduct

4. Double or triple damages as allowed by law;
5. Attorneys' fees, expenses, and costs of this action;
6. Pre-judgment and post-judgment interest in the maximum amount allowed by law; and
7. Such further relief as this Court deems necessary, just, and proper.

**JURY DEMAND**

Plaintiff demands a trial by jury of all claims asserted in this Complaint.

Dated: July 12, 2013

Respectfully submitted,

/s/ Raymond F. Chandler

Raymond F. Chandler, MoBar #57763

J. Mark Kell, MoBar #26413

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